Each tablet contains amlodipine maleate
equivalent to 5/ 10 mg amlodipine
-Regulation 11 and 12 update

PROPOSED FINAL PATIENT INFORMATION LEAFLET FOR AMLOC RANGE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

AMLOC 5 mg tablets

AMLOC 10 mg tablet

Read all of this leaflet carefully before you start taking AMLOC.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AMLOC** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT AMLOC CONTAINS:

The active substance in **AMLOC** is amlodipine.

Each **AMLOC 5 mg** contains amlodipine maleate equivalent to 5 mg amlodipine.

Each **AMLOC 10 mg** contains amlodipine maleate equivalent to 10 mg amlodipine.

The other ingredients are colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate.

AMLOC tablets are sugar free.

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2. WHAT AMLOC IS USED FOR:

- To treat high blood pressure (hypertension)
- To treat angina pectoris, which is characterised by chest pain and discomfort.

3. BEFORE YOU TAKE AMLOC:

Do not take AMLOC:

- If you are hypersensitive (allergic) to amlodipine, other calcium antagonists or any of the other ingredients in the tablets of **AMLOC.**
- If you have had shock which could include cardiogenic shock (this is the term used when blood pressure becomes so low that your heart stops working properly and medical treatment is required).
- You recently (within the past 28 days) suffered a heart attack.
- If you have unstable angina (chest pain which may occur when you are resting).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with AMLOC:

- If you are diagnosed as having a hypertensive crisis.
- If you have low blood pressure or other heart conditions.
- If you suffer from liver problems.
- If you suffer from severe kidney problems.
- If you have porphyria (a group of disorders that result in a buildup of chemicals called porphyrins in your body.
- If you are younger than 18 years of age.
- If you experience chest pain when taking **AMLOC**.
- If you are using lithium.

- If you suffer from diabetes.
- If you are more than 65 years of age.

Do not stop taking **AMLOC** without consulting your doctor as your symptoms may worsen

Taking AMLOC with food and drink:

AMLOC can be taken with or without food.

Pregnancy and breastfeeding:

Do not take **AMLOC** if you are pregnant, suspect that you are pregnant or breastfeeding your baby. Please consult your healthcare provider for advice before taking **AMLOC**.

If you are pregnant, or become pregnant whilst taking **AMLOC**, stop taking **AMLOC** and talk to your doctor as soon as possible.

Driving and using machinery:

AMLOC can cause dizziness. Do not drive or operate heavy machines until you know how **AMLOC** will affect you.

Taking other medicines with AMLOC:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Medicine that may influence **AMLOC**:

- Other medicines for hypertension (high blood pressure) or angina (chest pains) such as nitro-glycerine tablets under the tongue, long acting nitrates, beta-blockers or calcium channel blockers (such as verapamil, diltiazem), as this may increase the levels of **AMLOC** in the blood.

- Aldesleukin used in the treatment of kidney cancer and skin melanoma or medicines used to treat mental conditions (antipsychotics), as this may increase the levels of **AMLOC** in the blood.
- Medicines that alter the heart rate (such as quinidine or procainamide).
- Certain medicines used to treat fits (carbamazepine, phenobarbital, phenytoin), as these may reduce the effect of **AMLOC**.
- Sodium valproate (used for epilepsy) as this may increase **AMLOC** blood levels. (Discuss with your doctor if you are unsure).
- Medicines used to treat viral, fungal and bacterial infections (such as clarithromycin, erythromycin, ketoconazole, itraconazole or rifampicin) as these may lead to either increased or decreased levels of **AMLOC** in the blood.
- Rifampicin, St John's Wort (*Hypericum perforatum*), may give a lower plasma concentration of **AMLOC** in the blood.
- Ritonavir used in the treatment of HIV infections as this may lead to increased levels of **AMLOC** in the blood.
- Lithium, as this may result in toxic blood concentrations if used in combination with **AMLOC**.

4. HOW TO TAKE AMLOC:

Do not share medicines prescribed for you with any other person. Always take **AMLOC** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

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Adults:

A normal starting dose of 5 mg **AMLOC** once a day, taken at the same time every day with or without food.

The tablets should be swallowed whole, with a glass of water.

If no improvement is seen after 10-14 days, your doctor may increase the dose to the maximum of 10 mg **AMLOC** per day (taken as a single dose).

Elderly:

A lower starting dose may need to be taken.

Patients with kidney problems:

The normal adult dose can be used.

If you are undergoing dialysis speak to your doctor or pharmacist before taking **AMLOC**.

Patients with liver problems:

A lower starting dose may need to be taken.

Your doctor will decide on the dose depending on your condition.

If you have the impression that the effect of **AMLOC** is too strong or too weak, tell your doctor or pharmacist.

If you take more AMLOC than you should:

In the event of an overdose, with symptoms such as severe dizziness and fainting, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Your doctor will treat the symptoms of the side effects which may include marked and probably prolonged systemic hypotension (low blood pressure).

If you forget to take a dose of AMLOC:

If you forget to take a dose of **AMLOC**, take one as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet or tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

Effects when treatment with AMLOC is stopped:

It is important that you continue the course of treatment even if you begin to feel better after a few days. If your treatment with **AMLOC** is stopped suddenly, your chest pain may worsen.

5. POSSIBLE SIDE EFFECTS:

AMLOC can have side effects. Not all side effects reported for **AMLOC** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **AMLOC** please consult your healthcare provider for advice.

If any of the following happens, stop taking **AMLOC** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- Rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AMLOC**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Slow heartbeat (bradycardia) or rapid heartbeat (tachycardia), palpitations.

- Low blood pressure (hypotension) with symptoms such as fainting or light-headedness**.**
- High blood sugar levels (hyperglycaemia).
- Jaundice (yellow discolouration of the skin and eyes).
- Hepatitis, a liver condition, with symptoms such as stomach pain, fever, nausea, vomiting or loss of appetite.
- Weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis).
- Fainting (syncope).
- Kidney problems (passing less urine than is normal for you).
- Pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, increased heart rate and fever).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, dizziness and fatigue.
- Flushing.
- Stomach pain, nausea.
- Swelling in any part of the body.

Less frequent side effects:

- Abnormal blood test results.
- Breast enlargement in men.
- High cholesterol.
- Reduced sense of touch or sensation (numbness).
- Tingling sensation in hands, feet or lips (feeling of “pins and needles”).
- Involuntary trembling (tremors).

- Mood and/or sleep disorders.
- Sweating.
- Blurred vision, worsening eyesight
- Ringing in the ears (tinnitus).
- Cough.
- Inflammation of the mucous membrane in the nose (rhinitis).
- Constipation, vomiting, diarrhoea, indigestion.
- Dry mouth, swelling of the gums.
- Skin conditions such as rash, excessive skin pigmentation, hives, itchy skin.
- Joint pain, back pain, muscle pain, muscle cramps or weakness.
- Problems with sexual performance.
- Change taste perception (including loss of taste).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF AMLOC:

AMLOC should be stored in the original packaging (keep blisters in the carton until required for use) at or below 25 °C.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems

(e.g., toilets).

8. IDENTIFICATION OF AMLOC:

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AMLOC 5 mg: A white, round, slightly biconvex, bevelled edge tablet, scored on one side.

Diameter: 8,0 mm.

AMLOC 10 mg: A white, round, slightly biconvex, bevelled edge tablet, scored on one side.

Diameter: 10,0 mm.